DOM08 – Procedures for Quality Preventive Action

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1. Background

1.1. Quality preventive action is a proactive process to identify opportunities for improvement. All Department of Forensic Sciences (DFS) personnel are encouraged to identify needed improvements and potential sources of non-conformities, either technical or concerning the management system.

1.2. These procedures bring about continuous improvement through proactive measures, provide guidelines to identify potential nonconformities, and reduce the likelihood of nonconformities occurring. These procedures conform to the requirements of the Agency, government regulations, accreditation standards, and the applicable supplemental standards.

2. Definitions

2.1. For the purposes of this document, the following terms shall have the designated meanings:

DFS: Department of Forensic Sciences

Directorate: Key managerial personnel consisting of Directors, Deputy Director, the Chief Operating Officer and General Counsel

DOM: Departmental Operations Manual

QAM: Quality Assurance Manual

Q-PAR: Quality Preventive Action Request

3. Scope

3.1. These procedures are applicable to quality preventive actions identified by all DFS personnel.

4. Responsibilities

4.1. The **Division Director, Deputy Director, Directorate member** and/or **Manager/Supervisor** will:

4.1.1. Receive or initiate/designate initiation of a Q-PAR.

4.1.2. Ensure an individual or team is assigned the responsibility of handling the quality preventive action.

4.1.3. Specify the response due date and the time frame for the follow-up.

4.1.4. Ensure the adequacy of the quality preventive action plan.

4.1.5. Ensure the quality preventive action plan is implemented.

4.2. The **Quality Assurance Specialist** or designee will:

4.2.1. Ensure the progress of the quality preventive action is tracked and timelines are adhered to.

4.2.2. Ensure the effectiveness of the quality preventive action is verified.

4.3. **Individual(s)** and designees responsible for quality preventive action will:

4.3.1. Identify and report quality preventive actions to management.

4.3.2. Provide objective evidence of completion of the preventive action to the Deputy Director and the initiating Manager/Supervisor.

5. Procedures

5.1. If a condition or situation exists that may be improved, the DFS employee identifying the opportunity will notify their Manager/Supervisor, Division Director or the Deputy Director. If a quality preventive action is identified through an internal audit or assessment, the Manager/Supervisor and/or Directorate or designee member will initiate the Q-PAR.

5.2. Q-PAR

5.2.1. The Manager/Supervisor, Deputy Director or Designee will evaluate the proposed preventive action. If a Q-PAR is warranted, a person will be assigned to initiate the Q-PAR, develop the action plan and manage the preventive action. This form documents management approval for plan implementation and identifies the individual who is responsible for managing the quality preventive action, the specific milestone dates to track the progress of the chosen quality preventive action, and the date of completion of the quality preventive action steps.

5.3. Verification of Effectiveness

5.3.1. The Manager/Supervisor, Division Director, Deputy Director or designee will ensure the effectiveness of the quality preventive action is verified. This verification may be accomplished by reviewing the objective evidence of completion.

5.3.2. When the effectiveness of the quality preventive action has been verified, the Manager/Supervisor, Division Director, Deputy Director or designee shall inform the laboratory staff and/or individual analyst of the completion of the process. Memoranda are the method used to convey this information.

5.4. Monitoring

5.4.1. All approved action steps will be evaluated for completion and monitored for effectiveness. The Deputy Director or designee will ensure all due dates are monitored and adhered to. After a quality preventive action is completed and closed out, the Manager/Supervisor, Division Director, Deputy Director or designee will ensure monitoring is performed within the established time frame as necessary to assess its continued effectiveness. The monitoring may be accomplished by subsequent audits.

6. Documentation

6.1. The following records shall be generated and retained for at least one accreditation cycle or five years, whichever is longer:

6.1.1. Q-PAR with the associated responses.

7. References

7.1. ISO/IEC 17025– General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, (current revision)

7.2. ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).

7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

7.4. Division-specific Quality Assurance Manuals, (current revisions).

7.5. Record Retention Policy.